

Applicants: Charles S.H. Young and Peter J. Hoey
Serial No.: 09/904,669
Filed : July 13, 2001
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Objection under 37 C.F.R. §1.75(c)

The Examiner objected to claims 2-4, as allegedly being of improper dependent form for failing to further limit the subject matter of claim 1.

In response, but without conceding the correctness of the Examiner's objection, applicants note that claims 2-4 have been canceled and new claims 17-19 have been added in proper independent form, thereby obviating the objection.

In view of these remarks, applicants maintain that claims 17-19 satisfy the requirements of 37 C.F.R. §1.75(c).

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 2-4 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner alleges that these claims contradict a limitation of the claim from which they are dependent.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that claims 2-4 have been canceled and new claims 17-19 have been added in proper independent form, thereby obviating the rejection.

In view of these remarks, applicants maintain that claims 17-19 satisfy the requirements of 35 U.S.C. §112, second paragraph.

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Rejections under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 5 under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. Specifically, the Examiner states that the specification does not indicate the extent of the availability of the deposited modified adenovirus, VORF-6.

In response, applicants point out that the modified adenovirus designated VORF-6 has been deposited pursuant to the Budapest Treaty, on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure with the Patent Culture Depository of the American Type Culture Collection (ATCC), 10801 University Boulevard Manassas, VA 20110-2209 under ATCC Patent Deposit Designation Number PTA-2215. Applicants attach hereto as **Exhibit A** a copy of the Budapest Treaty Deposit Receipt and Viability Statement for the modified adenovirus designated VORF-6.

As indicated on the Budapest Treaty Deposit Receipt and Viability Statement, annexed hereto as Exhibit A, all restrictions on the availability to the public of the material deposited under ATCC Patent Deposit Designation Number PTA-2215 will be irrevocably removed upon issuance of a patent from the subject application. The deposits will be maintained by the ATCC for a period of 30 years from the date of deposit or at least 5 years after the last request for a sample of the deposited material, whichever is longer.

Where the ATCC cannot furnish samples of the above deposits for any reason, applicants shall make a replacement deposit of

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the material which was originally deposited within three months of receiving notification that the ATCC cannot furnish samples.

The Examiner further rejects claim 5 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleges that it is not clear in the specification that the virus of claim 5 meets the limitation of claim 1.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that claim 5 have been canceled and new claim 20 have been added in proper independent form, thereby obviating the rejection.

In view of these remarks, applicants maintain that claim 20 satisfies the requirements of 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claim 1 under 35 U.S.C. §103(a) as allegedly unpatentable over Gorziglia (1999) and Leppard (1997).

In response to the Examiner's rejection, applicants respectfully traverse, and maintain that the Examiner has failed to establish a *prima facie* case of obviousness.

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To establish a *prima facie* case of obviousness, the Examiner must demonstrate three basic criteria with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

In light of these requirements, applicants maintain that the cited references fail to support a *prima facie* case of obviousness for claim 1.

Claim 1 provides a modified adenovirus comprising genomic adenoviral DNA which has been modified to express only ORF-6 of the early region (E4).

The cited references, in combination, fail to teach all elements of the instant modified adenovirus. In particular, these references fail to teach that no other early or late gene products are expressed. The Examiner alleges that Gorziglia (1999) teaches a modified adenovirus which lacks the E1, E2A, E3 and the entire E4 region except ORF-3. In response, applicants direct the Examiner's attention to page 6048, second column, paragraph 3 of Gorziglia (1999), which describes the "vector (Av4orf3nBg) lacking E1, E2A, and all of E4 except ORF-3". Therefore, the virus of Godziglia (1999) possesses, in addition to the ORF-3 of E4, the early regions E2B, and E3. The Examiner concedes that the teachings of Goziglia (1999) are silent on the early region E2B, but alleges that the absence of expression of E2A is expected to

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abolish expression of E2B. However, applicants note that these vectors are grown in cell lines that complement these deficiencies. Accordingly, both the E2B and E3 region may be expressed in the presence of E2A and E1 genes, respectively. Applicants maintain that the requirement that no early or late gene other than ORF-6 of E4 be expressed as stated in (iii) of claim 1 is not taught in the cited references.

The Examiner also alleges that ORF-3 and ORF-6 of E4 have essentially similar roles in DNA replication, and it would therefore be obvious to substitute ORF-6 for ORF-3. In support, the Examiner cites Leppard. Leppard teaches the different roles of ORF-3 and ORF-6 in promoting viral gene expression and replication. Specifically, Leppard teaches that ORF-6 acts as a complex with the gene product of E1B. In response, applicants note that in the subject invention of claim 1, no E1B gene product is expressed. Therefore, the functions as detailed in Leppard could not be performed. Further, applicants note that the subject invention is based, in part, on applicants' discovery that the E4 ORF-6 product inhibits double-strand break repair. This function is not disclosed in Leppard. According to M.P.E.P. §2143, "[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Therefore, in light of the distinct functions of ORF-3 and ORF-6 enumerated in Leppard and absent applicants' discovery, there is no motivation to create a modified adenovirus that expresses only ORF6 of E4.

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For the reasons above, the cited references combined fail to teach the elements of the claimed modified adenovirus. Furthermore, absent the teachings in the subject specification, there could not have been a motive to combine or a reasonable expectation of success.

In view of the above remarks, applicants maintain that the Examiner has failed to set forth a *prima facie* case of obviousness, and that accordingly, claim 1 satisfies the requirements of 35 U.S.C. §103(a).

Conclusion

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the rejections, and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents,
Washington, D.C. 20231.

Alan J. Morrison
Reg. No. 37,399

04/14/03
Date

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EXHIBIT A

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Cooper & Dunham LLP
Attn: John P. White, Esq.
1185 Avenue of the Americas
New York, NY 10036

Deposited on Behalf of: The Trustees of Columbia University in the City of New York

Identification Reference by Depositor:

Human adenovirus type 5: VORF6

Ref: Docket or Case No.: 62530/JPW/EMW/MMM)

Patent Deposit Designation

PTA-2215

The deposit was accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposit was received July 11, 2000 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested October 17, 2000. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:


Fanya Nunnally, Patent Specialist, Patent Depository

Date: January 26, 2001